



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Minneapolis District Office  
Central Region  
250 Marquette Avenue, Suite 600  
Minneapolis, MN 55401  
Telephone: (612) 758-7114  
FAX: (612) 334-4142

May 5, 2009

**WARNING LETTER**

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

**Refer to MIN 09 - 18**

Ken Powell  
Chairman of the Board and CEO  
General Mills  
One General Mills Boulevard  
Minneapolis, Minnesota 55426

Dear Mr. Powell:

The Food and Drug Administration (FDA) has reviewed the label and labeling of your Cheerios® Toasted Whole Grain Oat Cereal. FDA's review found serious violations of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations (21 CFR). You can find copies of the Act and these regulations through links in FDA's home page at <http://www.fda.gov>.

**Unapproved New Drug:**

Based on claims made on your product's label, we have determined that your Cheerios® Toasted Whole Grain Oat Cereal is promoted for conditions that cause it to be a drug because the product is intended for use in the prevention, mitigation, and treatment of disease. Specifically, your Cheerios® product bears the following claims on its label:

- "you can Lower Your Cholesterol 4% in 6 weeks"
- "Did you know that in just 6 weeks Cheerios can reduce bad cholesterol by an average of 4 percent? Cheerios is ... clinically proven to lower cholesterol. A clinical study showed that eating two 1½ cup servings daily of Cheerios cereal reduced bad cholesterol when eaten as part of a diet low in saturated fat and cholesterol."

These claims indicate that Cheerios® is intended for use in lowering cholesterol, and therefore in preventing, mitigating, and treating the disease hypercholesterolemia. Additionally, the claims indicate that Cheerios® is intended for use in the treatment, mitigation, and prevention of coronary heart disease through lowering total and "bad" (LDL) cholesterol. Elevated levels of total and LDL cholesterol are a risk factor for coronary heart disease and can be a sign of

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coronary heart disease. Because of these intended uses, the product is a drug within the meaning of section 201(g)(1)(B) of the Act [21 U.S.C. § 321(g)(1)(B)]. The product is also a new drug under section 201(p) of the Act [21 U.S.C. § 321(p)] because it is not generally recognized as safe and effective for use in preventing or treating hypercholesterolemia or coronary heart disease. Therefore, under section 505(a) of the Act [21 U.S.C. § 355(a)], it may not be legally marketed with the above claims in the United States without an approved new drug application.

FDA has issued a regulation authorizing a health claim associating soluble fiber from whole grain oats with a reduced risk of coronary heart disease (21 CFR 101.81). Like FDA's other regulations authorizing health claims about a food substance and reduced risk of coronary heart disease, this regulation provides for the claim to include an optional statement, *as part of* the health claim, that the substance reduces the risk of coronary heart disease through the intermediate link of lowering blood total and LDL cholesterol. See 21 CFR 101.81(d)(2)-(3). Although the lower left corner of the Cheerios® front label contains a soluble fiber/coronary heart disease health claim authorized under 21 CFR 101.81, the two claims about lowering cholesterol are not made as part of that claim but rather are presented as separate, stand-alone claims through their location on the package and other label design features. The cholesterol claim that mentions the clinical study is on the back of the Cheerios® box, completely separate from the health claim on the front label. Although the other cholesterol claim is on the same panel as the authorized health claim, its prominent placement on a banner in the center of the front label, together with its much larger font size, different background, and other text effects, clearly distinguish it from the health claim in the lower left corner.

Additionally, even if the cholesterol-lowering claims were part of an otherwise permissible claim, under 21 CFR 101.81, the resulting claim language still would not qualify for the use of the soluble fiber health claim. To use the soluble fiber health claim, a product must comply with the claim-specific requirements in 21 CFR 101.81, including the requirement that the claim not attribute any degree of risk reduction for coronary heart disease to diets that include foods eligible to bear the claim. See 21 CFR 101.81(c)(2)(E). However, the label of your Cheerios® cereal claims a degree of risk reduction for coronary heart disease by stating that Cheerios® can lower cholesterol by four percent in six weeks. High blood total and LDL cholesterol levels are a surrogate endpoint for coronary heart disease; therefore, the cholesterol-lowering claims on the Cheerios® label attribute a degree of risk reduction for coronary heart disease because if total and LDL cholesterol levels decline, the risk of coronary heart disease declines as well.

**Misbranded Food:**

Your Cheerios® product is misbranded within the meaning of section 403(r)(1)(B) of the Act [21 U.S.C. § 343(r)(1)(B)] because it bears unauthorized health claims in its labeling. We have determined that your website [www.wholegrainnation.com](http://www.wholegrainnation.com) is labeling for your Cheerios® product under section 201(m) of the Act [21 U.S.C. § 321(m)] because the website address appears on the product label. This website bears the following unauthorized health claims:

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- "Heart-healthy diets rich in whole grain foods can reduce the risk of heart disease."

This health claim misbrands your product because it has not been authorized either by regulation [see section 343(r)(3)(A)-(B) of the Act [21 U.S.C. § 343(r)(3)(A)-(B)]] or under authority of the health claim notification provision of the Act [see section 343(r)(3)(C) of the Act [21 U.S.C. § 343(r)(3)(C)]]. Although FDA has issued a regulation authorizing a health claim associating fiber-containing grain products with a reduced risk of coronary heart disease (21 CFR 101.77), the claim on your website does not meet the requirements for this claim. For example, under section 101.77(c)(2), the claim must state that diets low in saturated fat and cholesterol and high in fiber-containing fruit, vegetable, and grain products may reduce the risk of heart disease. The claim on your website leaves out any reference to fruits and vegetables, to fiber content, and to keeping the levels of saturated fat and cholesterol in the diet low. Therefore, your claim does not convey that all these factors together help to reduce the risk of heart disease and does not enable the public to understand the significance of the claim in the context of the total daily diet (see section 343(r)(3)(B)(iii) of the Act [21 U.S.C. § 343(r)(3)(B)(iii)]).

In addition to the health claim authorized by regulation in 21 CFR 101.77, other health claims linking the consumption of whole grain foods to a reduced risk of heart disease have been authorized through the notification procedure in section 403(r)(3)(C) of the Act. Of those authorized claims, the one closest to the claim on your website states: "Diets rich in whole grain foods and other plant foods, and low in saturated fat and cholesterol, may help reduce the risk of heart disease."<sup>1</sup> Although the claim on your website also concerns whole grains and reduced risk of heart disease, it is different from the authorized claim in significant ways. To meet the requirements of the authorized claim, the claim must state that diets that are (1) rich in whole grains and other plant foods, and (2) low in saturated fat and cholesterol will help reduce the risk of heart disease. Instead, the claim on your website only states that diets rich in whole grains can reduce the risk of heart disease, with no mention of other plant foods or of low saturated fat and cholesterol.

- "Including whole grain as part of a healthy diet may ... [h]elp reduce the risk of certain types of cancers. Regular consumption of whole grains as part of a low-fat diet reduces the risk for some cancers, especially cancers of the stomach and colon."

This health claim misbrands your product because it has not been authorized either by regulation [see section 343(r)(3)(A)-(B) of the Act [21 U.S.C. § 343(r)(3)(A)-(B)]] or under authority of the health claim notification provision of the Act [see section 343(r)(3)(C) of the Act [21 U.S.C. § 343(r)(3)(C)]]. Although FDA has issued

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<sup>1</sup> See "Health Claim Notification for Whole Grain Foods with Moderate Fat Content," December 9, 2003 (<http://www.cfsan.fda.gov/~dms/flgrain2.html>).

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a regulation authorizing a health claim associating fiber-containing grain products with a reduced risk of cancer (21 CFR 101.76), the claim on your website does not meet the requirements for the authorized claim. For example, under section 101.76(c)(2) the claim must state that diets high in fiber-containing grain products, fruits, and vegetables may reduce the risk of some cancers. The claim on your website leaves out any reference to fruits, vegetables, and fiber content. Therefore, your claim does not convey that all these factors together help to reduce the risk of heart disease and does not enable the public to understand the significance of the claim in the context of the total daily diet [see section 343(r)(3)(B)(iii) of the Act [21 U.S.C. § 343(r)(3)(B)(iii)]].

In addition to the health claim authorized by regulation in 21 CFR 101.76, a health claim linking the consumption of whole grain foods to a reduced risk of certain cancers has been authorized through the notification procedure in section 403(r)(3)(C) of the Act. The authorized claim is: "Diets rich in whole grain foods and other plant foods ... may help reduce the risk of ... certain cancers."<sup>2</sup> Although the claim on your website also concerns whole grains and reduced risk of some cancers, it is different from the authorized claim in significant ways. For example, the authorized claim states that diets rich in whole grain foods and "other plant foods" may help reduce the risk for certain cancers. However, the claim on your website does not mention "other plant foods." Also, by using the language "especially cancers of the stomach and colon" the claim on your website emphasizes the relationship between whole grain foods and stomach and colon cancers as compared to other cancers, suggesting a greater degree of risk reduction or stronger evidence for the relationship between whole grain foods and risk of those two cancers. The claim authorized through the notification procedure does not emphasize the relationship between whole grain foods and stomach and colon cancer as compared to other cancers.

This letter is not intended to be an all-inclusive review of your products and their labeling. It is your responsibility to ensure that all of your products are in compliance with the Act and its implementing regulations.

Failure to promptly correct the violations specified above may result in enforcement action without further notice. Enforcement action may include seizure of violative products and/or injunction against the manufacturers and distributors of violative products.

Please advise this office in writing within 15 days from your receipt of this letter of the specific steps you have taken to correct the violations noted above and to ensure that similar violations do not occur. Your response should include any documentation necessary to show that correction has been achieved. If you cannot complete all corrections before you respond, state the reason for the delay and the date by which you will complete the corrections.

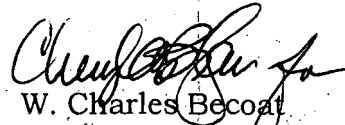
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<sup>2</sup> See "Health Claim Notification for Whole Grain Foods," July 1999  
(<http://www.cfsan.fda.gov/~dms/flgrain2.html>).

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Please send your reply to the attention of Tyra S. Wisecup, Compliance Officer, at the address in the letterhead. If you have any questions regarding this letter, please contact Ms. Wisecup at (612) 758-7114.

Sincerely,

  
W. Charles Becoat  
Director  
Minneapolis District

TSW/ccl

TGP  
(ADCE)